REMARKS

Claims 1-20 remain in this application. Claims 1-3, 6-7 and 12 have been amended. Support for the amendments to claims 1-3 and 12 may be found, for example, on page 7:2-9, Table I and claim 3 of the application as filed. Support the amendments to claims 6 and 7 may be found, for example, at page 8:7-16 and Table II of the application. By these amendments, no new matter has been added.

Claims 1-20 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite, because of the phrase "a person in need of a lighter skin tone" in claim 1. These rejections are respectfully traversed. Without making any concession as to definiteness of the cited phrase, claim 1 has been amended to define "delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of the effective amount," etc. Claim 1 as amended has a clear and definite meaning, defining a purpose and procedure for delivering the effective amount of MSM. Both the purpose and procedure are definite and clear. Therefore, these rejections should be withdrawn.

Claims 1-7 and 10 stand rejected under 35 U.S.C. § 102(b) as anticipated by Herschler (US 4296130). These rejections are respectfully traversed. Herschler fails to disclose or suggest the element of "**delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of the effective amount, at least until the person develops a skin tone noticeably lighter than before commencement of the delivery step**," as defined by claim 1. As acknowledged in the office action, none of the references, including Herschler, recognize any usefulness for MSM in lightening of skin tone. Nor is it true that noticeable skin lightening would inherently – that is, necessarily – occur using any of the topical or oral administrations taught by Herschler. As demonstrated by the examples in the present application, MSM may, or may not, cause noticeable skin lightening, depending on the dose, route of administration, and duration of administration. There is

absolutely nothing in the record to contradict this fact.

In addition, there has been no showing that any of the methods of administration of Herschler would yield a noticeable lightening of skin tone. Most of the specific examples disclosed by Herschler do not include a defined period of application to a human subject. Those few examples that do define such a period – specifically, Examples 6 and 9 – disclose topical-only administration for a period of three weeks or less. These examples are not relevant to a claim that requires ingestion; moreover, there is no evidence that the dosing regimens of Examples 6 and 9 would result in noticeable skin lightening. To the contrary, the evidence in the present application suggests that ingestion of a specific minimum dose for a period of about three months may be required.

Herschler is also deficient in disclosing an effective dosing schedule for skin lightening via ingestion. Herschler's sole example of oral ingestion concerns only rats for a period of six weeks, as a safety study. Example 16, col. 11. Herschler reports only that "[a]fter six weeks of administration, none of the animals had died or displayed unusual symptoms or behavior." Col. 11:60-61. However, the dosage used of 20g/kg/day is clearly much too high to be relevant to human dosing, and far outside the range of any reported testing. What effect Herschler's reported dosing and administration period used only on rats would have on humans is simply unknown. Therefore, the necessary showing of inherent result has not been made, and Herschler fails to disclose the claimed delivering of an effective dose to a person "**by ingestion of the effective amount**."

In view of the deficiencies of Herschler outlined above, it cannot anticipate claim 1, which is therefore allowable. Claims 2-20 are also allowable, at least as depending from an allowable base claim. These rejections should therefore be withdrawn.

In addition, with respect to claim 3, Herschler, like the other references, fails to disclose or suggest the claimed dosing regimen of "**ingestion of a dose within a range of 20 to 150 mg/kg per day**." Herschler primarily teaches topical administration of

MSM to humans, although it does mention oral administration at col. 2:41-46. However, Herschler does not teach the claimed dose via ingestion or otherwise. As noted above, the only specific ingestion dose Herschler teaches is 20g/kg/day to rats for six weeks, which is far removed from what is claimed. Herschler is therefore further deficient with respect to claim 3, and cannot be said to anticipate it.

Claims 6 and 7 are also independently allowable. These claims define a combined oral and topical administration. Herschler nowhere discloses combined topical and oral administration, and therefore also cannot anticipate these claims, for independent reasons.

Claims 1 and 4 - 6 stand rejected under 35 U.S.C. § 102(b) as anticipated by Kuhnau (US 2002/0142019). These rejections are respectfully traversed.

Kuhnau plainly teaches only topical administration of MSM. See, e.g., ¶ [0001]. Therefore, Kuhnau cannot anticipate claim 1, which defines delivering an effective amount to a person "**by ingestion of the effective amount**." Claim 1 is therefore allowable over Kuhnau. The remaining claims are also allowable, at least as depending from an allowable base claim. These rejections should therefore be withdrawn.

Claims 1 and 5 – 6 stand rejected under 35 U.S.C. § 102(b) as anticipated by Scott (US 6183758). These rejections are respectfully traversed. Like Kuhnau, Scott teaches only topical administration via a "skin absorbent cream." See, e.g., Abstract. Scott therefore cannot anticipate claim 1, which defines delivery by ingestion. Claim 1 is therefore allowable. The remaining claims are also allowable, at least as depending from an allowable base claim. These rejections should therefore be withdrawn.

Claims 1-7 stand rejected under 35 U.S.C. § 102(b) as anticipated by Charters (US 6541045). These rejections are respectfully traversed. Although Charters teaches oral administration of MSM, it fails to disclose administration "**by ingestion of the effective amount,**" as defined by claim 1. The only specific dosing regimens disclosed by Charters are found in its Comparative Examples 1 and 4. Cols. 11-12. In Comparative Example 1, Charters discloses a tablet that includes 400 mg of MSM. For

a 45 kg person, a dose of 400 mg amounts to 8.9 mg/kg, far less than any effective amount identified by the present application. In addition, Charters fails to disclose the number of tablets to be taken daily, or for what period. In Comparative Example 4, Charters merely discloses an even lower dose of 333 mg in a tablet. Therefore, Charters fails to disclose or suggest delivering an effective amount for skin lightening by ingestion, as defined by claim 1. Charters therefore cannot anticipate claim 1, which is therefore allowable. The remaining claims are also allowable, at least as depending from an allowable base claim. These rejections should therefore be withdrawn.

In addition, Charters fails to disclose or suggest the specific dosage range of 20 to 150 mg/kg/day specified by claim 3, or the combination of oral and topical administration defined by claims 6 and 7. At least these claims are therefore independently allowable.

Claims 8, 9, 11, 12 and 17-20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Herschler and Kirby (US 6444234). These rejections are respectfully traversed.

As shown above, Herschler fails to disclose all of the elements of independent claim 1, and other claims. Kirby does not make up for these deficiencies, merely teaching use of a transdermal patch for delivery of pharmaceutical agents. Therefore, Herschler and Kirby cannot render claim 1 obvious, which is therefore allowable. Claims 8, 9, 11, 12 and 17-20 are also allowable, at least as depending from an allowable base claim. These rejections should therefore be withdrawn.

Claims 13-16 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Herschler and Flick (NPL Cosmetic and Toiletry Formulations). These rejections are respectfully traversed.

As shown above, Herschler fails to disclose all of the elements of independent claim 1, and other claims. Flick does not make up for these deficiencies, merely teaching, in relevant part, that glycolic acid may be used as an exfoliate. Failing to disclose all elements of claim 1, Herschler and Flick cannot render claim 1 obvious,

which is therefore allowable. Claims 13-16 are also allowable, at least as depending from an allowable base claim. These rejections should therefore be withdrawn.

* * *

In view of the foregoing, the Applicants respectfully submit that Claims 1-20 are in condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested, and a timely Notice of Allowability is solicited.

The arguments presented herein are sufficient to fully traverse the rejections set forth in the Office Action. Therefore, Applicants have not presented all possible arguments, and may not have refuted the characterizations of either the claims or the prior art as may be found in the record. However, the lack of such arguments or refutations is not intended to waive such arguments or indicate concurrence with such characterizations.

To the extent it would be helpful to placing this application in condition for allowance, the Applicants encourage the Examiner to contact the undersigned counsel and conduct a telephonic interview.

While the Applicants believe that no fees are due in connection with the filing of this paper, the Commissioner is authorized to charge any shortage in the fees, including extension of time fees, to Deposit Account No. 50-3683.

Respectfully submitted,

Date: October 8, 2008

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